## Message

From: Kraft, Andrew [Kraft.Andrew@epa.gov]

**Sent**: 10/29/2013 1:02:18 PM

To: Rieth, Susan [Rieth.Susan@epa.gov]; Whalan, John [Whalan.John@epa.gov]

CC: Glenn, Barbara [Glenn.Barbara@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]; Makris, Susan

[Makris.Susan@epa.gov]

Subject: RE: Wednesday's IRIS all hands meeting topic: study quality evaluation tables PLEASE READ -- I NEED YOUR INPUT

ON TUES! (thank you...)

Attachments: Toxicological Study Evaluations excerpt AK102813.docx

Sue,

Here is an excerpt of our DRAFT<sup>®</sup> table for experimental studies examining nervous system effects of inhaled formaldehyde (note: there is a separate, but similar, table that evaluates the mechanistic data relevant to inhalation exposure- as the potential MOA for systemic effects of inhaled formaldehyde is a critical issue in this assessment). I tried to include experiments assessing different apical endpoints to provide a more varied set of considerations. The other health outcomes discussed in the assessment use an identical format, although some of the specific considerations (particularly under study design and endpoint evaluation) can vary substantially.

Please feel free to share within NCEA with the caveat that this table is still under development, and let me know if you need anything else.

Best, Andrew

From: Rieth, Susan

Sent: Monday, October 28, 2013 5:23 PM

**To:** Whalan, John **Cc:** Kraft, Andrew

Subject: RE: Wednesday's IRIS all hands meeting topic: study quality evaluation tables PLEASE READ -- I NEED YOUR

INPUT ON TUES! (thank you...)

Thanks John. Andrew, I certainly don't want to put you and others working of study quality tables on the spot, but sounds like the timing might be good. And I have to say that I don't think we can have this discussion without input from the FA team. But I also don't want anyone to be burdened with much preparation for Wednesday's IRIS all hands meeting. Is it do-able for those on the FA team to contribute to the Wed meeting? I'll gladly pull the materials together and distribute them as long as you and others are willing to discuss the tables. In particular, I think it will be important to discuss how you decided on the content of the cells.

Let me know if this plan sounds ok to you. I'm keeping my expectations for this conversation in check, but I am anxious to get the conversation kick started.

Thanks!

Sue

From: Whalan, John

**Sent:** Monday, October 28, 2013 5:03 PM

**To:** Rieth, Susan **Cc:** Kraft, Andrew

Subject: RE: Wednesday's IRIS all hands meeting topic: study quality evaluation tables PLEASE READ -- I NEED YOUR

INPUT ON TUES! (thank you...)

Sue,

Andrew Kraft, Sue Makris, Brian Pachkowski, and I met this morning to discuss study quality tables for formaldehyde. Andrew has the latest and greatest tables. I think you will find they are the most thoughtfully designed tables to date.

John

From: Rieth, Susan

**Sent:** Monday, October 28, 2013 4:55 PM

To: D'Amico, Louis; Kraft, Andrew; Makris, Susan; Whalan, John; Glenn, Barbara; Fritz, Jason

Cc: Chiu, Weihsueh; Strong, Jamie; Gehlhaus, Martin; Luke, April; Cooper, Glinda

Subject: Wednesday's IRIS all hands meeting topic: study quality evaluation tables PLEASE READ -- I NEED YOUR

INPUT ON TUES! (thank you...)

Hi all,

Because I recently raised to Vince my observation that there's considerable angst across the IRIS Program regarding study quality evaluation tables for animal studies, I was tasked with leading a discussion of this topic at this Wednesday's IRIS all hands meeting. (you'd think I'd learn...) With Wed just a couple of days away, I'm finally writing to those of you who I know have done some thinking about generating animal study quality evaluation tables and have worked on tables for your chemical. This discussion will be limited to animal study tables only. We won't be including epid tables specifically in this discussion, but lessons learned over the evolution of those tables would be valuable to share.

For Wed's all hands, I'd like to show some examples of study quality tables that have been developed in house. So, I'm asking those of you who've developed these tables to forward an example or two to me. If the table is too long, I'll extract a representative page. I'd also ask that you spend about 5 minutes or so walking through your example table and briefly discuss how you arrived at this type of table.

I'll provide some a couple of intro slide regarding the goal of the discussion and some general considerations. I don't expect we'll resolve all questions about these tables, but I hope we have some good direction by the end of the meeting.

Finally... if I've overlooked someone who's worked on these tables, please pass along this email. Additional example tables would be welcomed.

My apologies for the late email, but I hope this isn't going to be burdensome in any way. I really appreciate your contributions to this discussion.

Thanks!

Sue